RESEARCH ON ORAL BONE LOSS AND OSTEOPOROSIS

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PURPOSE

The National Institute of Dental Research (NIDR) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invite grant applications to conduct multidisciplinary research, both basic and clinical, with emphasis on genetic and epidemiological aspects of the link between osteoporosis and oral bone loss.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Osteoporosis and Oral Bone Loss, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, non-profit and for-profit, public and private organizations, such as dental or medical schools, universities and research institutions.

Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms available for the support of this program include the research project grant (R01), First Independent Research Support and Transition (FIRST) Award (R29), small grant (R03) (NIDR only), and Interactive Research Project Grants (IRPG).

Applications from institutions that have an Osteoporosis Research Center funded by the NIAMS may wish to identify the center as a resource for conducting the proposed research. If so, a letter of agreement from both the center director and program director should be included with the application.

RESEARCH OBJECTIVES

Osteoporosis is a major health problem in the United States affecting an estimated 20 million people, many of whom are women. The disease is implicated in 1.5 million fractures each year and accounts for medical care expenditures of at least $10 billion annually. In addition, there is evidence of significant mortality and morbidity associated with osteoporosis. While little is known about the possible relationship between oral bone loss and osteoporosis, the scientific literature suggests that skeletal osteopenia, in concert with underlying factors, may create an environment conducive to accelerated loss of oral bone. In the dentate this may be manifested as a loss of tooth support. In toothless (edentulous) individuals, osteopenia may augment local anatomic, biological, and mechanical factors resulting in extensive ridge atrophy. Thus, skeletal osteopenia may influence the need for and outcome of periodontal, pre-prosthetic, and implant procedures. There is also evidence in the literature to suggest that therapeutic measures that control or have an effect on osteoporosis could have a favorable impact on oral bone retention.

An NIH workshop titled "Osteoporosis and Oral Bone Loss" was sponsored by the National Institute of Dental Research, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the Office of Research on Women's Health, to bring together experts from various disciplines to focus attention on the possible relationship between osteoporosis and oral bone loss. The goal of the workshop was to summarize the state of the science on this relationship, to identify gaps in knowledge regarding possible linkages underlying the relationship, and to develop specific research recommendations for the future. The complete proceedings of the workshop

and the research recommendations will be published in an upcoming supplement to the Journal of Bone and Mineral Research.

While craniofacial bone may provide measurable features indicative of skeletal bone health, studies specifically designed to examine the relationship between craniofacial bone mass and osteoporosis have had mixed results and have been plagued by methodological deficiencies that cloud interpretation and prohibit comparison of results. Thus, many of our concepts are based on anecdotal information, clinical impressions, and studies on small sample sizes. Recognizing these limitations, the literature shows that there is: (1) a positive correlation between tooth loss, edentulism, and osteoporosis; (2) a relationship between skeletal, maxillary, and mandibular bone mass; (3) annual decrease in jaw bone of elderly individuals, the rate of decrease being greater in women than in men; (4) a significant difference between younger and older women in maxillary and mandibular alveolar bone; and (5) a significant difference in osseous fractal dimensions in premenopausal and postmenopausal women. Thus, despite the limited data available, it was the consensus of the workshop that the rate and severity of oral bone loss might be accelerated by the presence of various forms of osteoporosis. These data as well as our knowledge of basic bone biology suggest a strong rationale for a relationship between oral bone loss and osteoporosis.

The participants in the workshop on Osteoporosis and Oral Bone Loss described the need for continued integration of insights from collaborative studies carried out by specialists in oral biology and medicine and experts in skeletal osteoporosis. Some recommended research directions include, but are not limited to:

o Development of new and improved methods for quantitatively assessing oral bone volume, density, structural and mechanical properties, quality and turnover applicable to both dentate and edentate individuals. These methods should be suitable for large scale population studies.

o Development of in vitro and in vivo models for studying oral bone loss and remodelling. Models that investigate the effect of mechanical, biophysical and metabolic influences on oral bone are encouraged.

o Identification and development of molecular markers present in the oral cavity that can be used for the diagnosis of oral and non-oral bone loss.

o Development of basic knowledge on the similarities and differences between oral and non-oral bone in health and disease and investigate possible relationships between osteoporosis and oral bone loss.

o Design of epidemiological and genetic studies to elucidate possible linkages between oral bone loss and osteoporosis.

o Development of simple, cost-effective, accurate and safe diagnostic tests to ascertain individuals at risk for oral bone loss.

o Conducting studies to clarify the role of fluorides in the possible prevention of osteoporosis and, specifically, oral bone loss.

o Identification and characterization of association between osteoporosis and periodontal diseases.

These areas of research are neither prioritized nor meant to be restrictive. Investigators are encouraged to submit scientifically meritorious applications in any area of research responsive to the general research objectives of this Program Announcement.

Research applications should be of high scientific quality. The project should be founded on a strong hypothesis as evidenced by preliminary data collected by the investigator or others. Prior experience of the investigative team is an important element in proving the likely success of the research proposed.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical

research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample site appropriate for the scientific objectives of the study. This information should be included in form PHS 398 (rev.9/91) in items 1-4 of the Research Plan and summarized in item 5, Human Subjects. Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all such projects to include representation of the full array of United States racial, ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed or the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to the NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on grant application form PHS 398 (rev. 9/91), which may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/435-0714 and from the institution's office of sponsored research. To identify the application as a response to this PA, check "yes" on item 2a of face page of the application and enter PA-93-104 "Osteoporosis and Oral Bone Loss".

Applications for the R01 and R29 mechanisms will be accepted at the standard applications receipt dates indicated in the application kit.

The application receipt date for R03s is April, August, and December 3.

The receipt dates for the IRPG mechanism (which was announced in the NIH Guide, Vol. 22, No. 16, April 23, 1993) are February, June, and October 15.

Submit a signed, typewritten original of the application, and five signed photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by initial review groups of the Division of Research Grants, NIH or by the review group of the relevant Institute in accordance with the standard NIH peer review procedures. Following scientific-technical review, applications will receive a second level review by the appropriate national advisory council or board.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions:

o Quality of the proposed project as determined by peer review

o Availability of funds

o Program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

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Direct inquiries regarding fiscal matters to:

Ms. Theresa Ringler
Grants Management Office

National Institute of Dental Research
Westwood Building, Room 510
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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158,(42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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